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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,119	03/31/2004	Tian Wen	20335-00186	6566

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WESTBOROUGH, MA 01581

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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12/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,119

Applicant(s)

WEN ET AL.

Examiner

Blessing M. Fubara

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 23 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of response to election/restriction requirement of 09/05/07, amendment and remarks filed 9/14/07. Claims 1-21 and 29-64 are canceled. Claim 24 is withdrawn. Claims 22-28 are pending.

Election/Restrictions

1. Applicant's election without traverse of claims 22-28, Group II, in the reply filed on 09/14/07 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 22, 23 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The boundaries for protection sought by applicant for "penetration enhancer" and "shear-thinning polysaccharide gum" in claim 22 are not discernible making the scope of the claims unclear and indefinite.

4. Applicant may overcome the rejection by using Markush language, if applicant so desires, to claim what the penetration enhancer and shear-thinning polysaccharide are, and making sure that the amendment does not introduce new matter into the claims and specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 22, 23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Buyuktimkin et al. (US 6,046,244).

Buyuktimkin provides a semi solid composition comprising prostaglandin E₁ for sustained delivery of the prostaglandin E₁ that addresses transdermal/topical delivery of prostaglandin E₁, which Buyuktimkin recognizes is a “vasodilator useful to maintain open blood vessels and therefore, to treat peripheral vascular disease among other ailments. While the potential benefits from transdermal delivery of prostaglandin” E₁ “have long been recognized, prior efforts at developing a topical composition for prostaglandin delivery have not been fully successful,” (column 1, lines 27-34) with the prostaglandin” E₁ meeting claim 25. The composition of Buyuktimkin comprises prostaglandin E₁, polysaccharide gum, lipophilic compound, penetration enhancer and buffer system that is capable of buffering the composition at a pH of about 3 to about 7.4 (abstract; column 2, lines 9-28) meeting claim 22. The composition is applied to the skin of a patient (column 8, lines 1-19) meeting the method of claim 22 and the tissue requirement of claim 23 since the purpose of Buyuktimkin is to transdermally administer prostaglandin containing composition to treat peripheral vascular disease to maintain open blood vessels. Specific polysaccharide present in the composition of Buyuktimkin is galactomannan (column 2, line 49; column 5, lines 37-58) meeting the polymer thickener of claim 22. The penetration enhancer is substituted alkanoate such as dodecyl 2-(N,N dimethylamino)-propionate (DDAIP) (column 3, lines 5-54) meeting claims 26 and 27. The lipophilic component is aliphatic C₁-C₈ alcohol or aliphatic C₈-C₃₀ ester (abstract; column 2,

lines 15-17; column 6, lines 28-31) meeting claims 22 and 28. Buyuktimkin meets the limitations of the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 22, 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buyuktimkin et al. (US 6,046,244) in view of Clifford et al., ("Treatment of vasospastic disease with prostaglandin E₁," in Br Med J. 1980 October 18; 281(6247): 1031-1034).

Buyuktimkin is described above as disclosing a composition comprising prostaglandin E₁, penetration enhancer, polymer thickener, lipophilic component and buffer system that maintains the composition at a pH of about 3 to about 7.4 for the purpose of transdermal/topical administration for treating conditions that are treatable with prostaglandin E₁ such as maintaining

open blood vessels (column 1, lines 27-33) and male impotency and other ailments (column 8, lines 6-8). Although, Buyuktimkin does not use the term vasospasm, keeping open blood vessels is treating narrowing of the blood vessels. However, Clifford discloses that prostaglandin E₁ is a vasodilator and potent inhibitor of platelet aggregation and is used to treat vasospastic disease. Therefore, transdermal application of a composition comprising a known vasodilator, prostaglandin E₁, would maintain open blood vessels as taught by Buyuktimkin and therefore treat vasospasm when applied to the skin of a patient (column 8, line 12 of Buyuktimkin) as evidenced by the positive teaching of treating vasospastic disease with prostaglandin E₁. Therefore, taken the teaching of Buyuktimkin in view of the evidence provided by Clifford, the ordinary skilled artisan would reasonably expect to successfully treat vasospasm or maintain open blood vessels by transdermally/topically applying the semi solid composition of Buyuktimkin to the skin of a patient.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

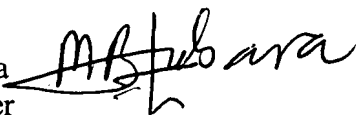
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/815,119
Art Unit: 1618

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.